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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,555	07/16/2004	Bo Johan Niklas Niklasson	10400-000111/US	5132

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EXAMINER

EISEMAN, ADAM JARED

ART UNIT	PAPER NUMBER
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3736

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04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,555	Applicant(s) NIKlasson, BO JOHAN NIKLAS	
	Examiner ADAM J. EISEMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendments and arguments/remarks filed on 1/28/2009.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 11, 15, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al (US Patent 5,044,372) in view of Liedtke (US Patent 4,765,986).

5. Anhauser discloses an epicutaneous test plaster, comprising: a flexible carrier (12) including an adhesive layer (13) for removably adhesion of the epicutaneous test plaster to a skin portion; a plurality of test chambers (around 14) distributed over the adhesive layer of the carrier; a removable cover layer (16) extending over all the test chambers and the carrier, wherein the test chambers are formed as separate chambers,

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each test chamber including, a support element (14) secured to the carrier and including a support layer adhered to a moisture barrier layer (column 5, line 30), a frame-shaped plastic layer (15) secured on top of and embracing the support element and defining at least some sidewalls of the test chamber that directly confront each other (see figure 1), and wherein the cover layer is removably secured by way of the adhesive layer of the carrier. In regards to claim 11, each support element is secured to the carrier by way of an adhesive layer, whose one side is fixed to the carrier and whose other side is fixed to the support element. In regards to claim 15, each frame-shaped plastic layer is secured to the support element by way of an adhesive layer, whose one side is fixed to the plastic layer and whose other side is fixed to the support element.

However, Anhauser does not expressly disclose that a first layer of adhesive is on the outwardly directed side of the frame-shaped plastic layer, that the frame-shaped plastic layer is foam, or a second layer of adhesive between the foam plastic layer the support element.

Liedtke teaches a layer of adhesive (11) on the skin contacting side of a frame-shaped foam plastic layer (10) of a medical plaster (column 5, lines 35-61; figures 4 and 5). The adhesive layer is for attaching the plastic layer to a test area (column 5, lines 35-61). The adhesive layer extends all the way around the perimeter of the foam layer and has an opening through which a chamber is exposed (column 5, lines 35-61). Liedtke also teaches a moisture barrier element (9) for containing the substance in the plaster and preventing it from leeching into the adhesive (column 5, lines 35-61).

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Regarding claims 1, 11, 15, and 18-20; it would have been obvious to one having ordinary skill in the art at the time of invention to substitute Anhauser's frame-shaped plastic layer test chamber and support element with Liedtke's frame-shaped foam plastic layer and moisture barrier element test chamber having a layer of adhesive on the outwardly directed side of the frame in order to prevent leeching of the testing material in the chamber from the adhesive and provide direct adhesion of the frame to skin to prevent leakage of the testing material. This is substitution of one known element for another to obtain predictable results. Furthermore, it would have been obvious to one of ordinary skill in the art to modify Liedtke's moisture barrier element to extend under the frame shaped foam plastic layer in order to provide more coverage and further prevent leeching of the testing material to the adhesive layer. It would have been obvious that such a modification would require disposing an adhesive layer between the moisture barrier/support element and foam layer to ensure the foam layer is attached to the carrier as it is well known in the art to use an adhesive to connect elements to prevent removal.

6. Claims 2-4, 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Rudiger et al. (US 4,887,611).

Anhauser as modified by Liedtke does not expressly disclose that the cover layer is a plastic layer with blister bubbles.

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Rudiger teaches an upper plastic cover layer (column 3, lines 44-47) with blister bubbles (20) and a lower cover layer, which enclose test chambers. The blister bubbles have a groove (see above 19 in figure 3) in contact with a rim of the test sites. The cover layer of Rudiger improves handling, storage and transport of the plaster (column 3, lines 39-49).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted an upper cover layer with blister bubbles and a lower cover layer as taught by Rudiger for the cover layer of Anhauser as modified by Liedtke in order to achieve the predictable result of enclosing the plaster for handling, storage, and transport purposes.

In regards to claim 3, Rudiger discloses that the cover layer has a polypropylene layer but does not expressly disclose that the cover layer has a polyethylene layer. However, Rudiger states that the cover layer should be coated with an inert material (column 3, lines 45-46). Rudiger further teaches that polypropylene and polyethylene are alternative inert plastics (column 2, lines 44-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the polypropylene on the cover layer with polyethylene because the substitution would have yielded predictable results and because Rudiger teaches that these two materials are alternative inert plastics. Furthermore, Liedtke teaches that the cover layer and base layer are an occlusive plastic foil (column 5, lines 35-57). Thus it would have been obvious to one of ordinary skill in the art to use a plastic foil instead of a metal foil as

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taught by Rudiger as substitution of one known element with another with predictable results.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Quisno (US 4,450,844).

Even though Anhauser states that various materials can be used (column 3, lines 26-31), including treated papers, Anhauser as modified by Liedtke does not expressly disclose that the cover layer is a paper liner with a silicone layer that faces the test chambers.

Quisno teaches a paper cover liner with a silicone layer that faces test areas (column 4, lines 33-37).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the paper liner taught by Quisno for the cover layer of Anhauser as modified by Liedtke because the substitution would have yielded predictable results such as protecting the adhesive until use.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Hoffmann (US RE37,934).

Although Anhauser discloses a flexible porous surgical tape, Anhauser as modified by Liedtke does not expressly disclose a methacrylate-based adhesive layer.

Hoffmann teaches a methacrylate-based adhesive layer (column 7, lines 13-26) for fixing a plaster to the skin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the methacrylate-based adhesive as taught by Hoffmann for the adhesive of Anhauser as modified by Liedtke to achieve the predictable result of adhering a plaster to skin.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Breneman (US 4,543,964).

Anhauser as modified by Liedtke teaches using a cotton support element (column 5, line 29), but does not expressly disclose that the support element is cellulose-based.

Breneman teaches that cotton and methyl cellulose are known alternative absorbent materials for use in a test plaster (column 4, lines 15-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted a cellulose-based material as taught by Breneman for the cotton of Anhauser as modified by Liedtke to achieve the predictable result of providing an absorbent material to hold a test substance.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of van der Bend (NL 8701577).

Anhauser as modified by Liedtke does not expressly disclose that the frame-shaped foam plastic layer consists of a polyethylene foam.

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van der Bend teaches making a frame-shaped foam plastic layer out of a polyethylene foam (see translation submitted by Applicant).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a polyethylene foam as taught by van der Bend in the frame-shaped foam plastic layer of Anhauser as modified by Liedtke because it is well-known and routine in the art to substitute alternative materials to yield predictable results.

11. Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Pluim, Jr. (US 4,472,507).

In regards to claim 13, the frame-shaped foam fixing layer of Anhauser extends outside the rim portions of the support element. Anhauser as modified by Liedtke does not expressly disclose that the support element is secured to the carrier by a flexible double-adhesive tape or that the frame-shaped foam plastic layer is secured to the support element by a flexible double-adhesive tape.

Pluim teaches the use of a flexible double-adhesive tape for use in adhering layers of a carrier together (column 3, lines 17-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a flexible double-adhesive tape as taught by Pluim in the plaster of Anhauser as modified by Liedtke to achieve the predictable result of adhering layers together.

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12. Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986) and Pluim, Jr. (US 4,472,507), as applied to claims 9, 12 and 13 above, and further in view of Kurokawa et al. (US 4,158,359).

Anhauser as modified by Liedtke and Pluim does not expressly disclose using a synthetic rubber-based adhesive on the double-adhesive tape.

Kurokawa teaches that synthetic rubber is a known pressure-sensitive adhesive that has no influence on human skin (column 5, lines 33-38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a synthetic rubber-based adhesive as taught by Kurokawa in the plaster of Anhauser as modified by Liedtke and Pluim to achieve the predictable result of adhering layers together with no influence on human skin.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhauser et al. (US 5,044,372) as modified by Liedtke (US 4,765,986), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Kraft et al. (US 4,809,707).

Anhauser as modified by Liedtke does not expressly disclose that the frame-shaped foam plastic layer is a flexible double-adhesive tape.

Kraft teaches a flexible double-adhesive tape (46) surrounding a support element for the purpose of affixing the support element to a patient (column 4, lines 12-14).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have made the frame-shaped foam plastic layer of Anhauser as modified

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by Liedtke out of double-adhesive tape as taught by Kraft to achieve the predictable result of affixing a support element to a patient.

Response to Amendment

14. The applicant's amendment's, arguments, and remarks have been considered but are moot in view of the new rejections described above.

The new grounds of rejection are presented above.

The applicant's argument that substitution of Anhauser's plastic layer with Liedtke's plastic layer is not simple substitution is found to be non persuasive. The argument is non persuasive as the motivation for the substitution of Anhauser's plastic layer with Liedtke's plastic layer is to provide an outer facing adhesive which connects the foam plastic layer to the skin and creates a more isolated test chamber between the carrier and the skin.

The applicant's argument that the sidewalls do not directly confront each other is non persuasive as the examiner is only incorporating the foam plastic ring which is for containing a material for delivery to the skin. One of ordinary skill in the art would realize that any amount of test material (or no material at all) may be present in the test chamber created by the foam plastic ring. Thus the sidewalls of the test chamber directly confront each other in the absence of test material (as is in the spirit of Anhauser's test plaster).

The applicant's argument Anhauser and Liedtke take mutually exclusive paths to reach different solutions to different problems is non persuasive. One of ordinary skill in the art at the time of the invention would realize in the broadest reasonable

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interpretation, both Anhauser and Liedtke provide devices for attachment to the skin comprising a compartment for delivering a material to the skin, thus they share the comment problem and solution of delivering materials to the skin through adhesive attachment to the skin. Furthermore, the means plus function does not prohibit the use of Liedtke as it provides means for adhesively connecting to the skin and one of ordinary skill in the art at the time of the invention would not distinguish between a test area and therapeutic area as they are areas where a material contained in a chamber is delivered to the skin.

Finally, the applicant's argument that the primary reference of Anhauser teaches away from the modification is non-persuasive. One of ordinary skill in the art at the time of the invention would realize that in modifying Anhauser with Liedtke, one would use a similar cover layer as described in Liedtke, which is a foil cover which is easily removed from the outwardly facing adhesive, thus not affecting the force required to remove the cover layer.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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5/25/2009

/A. J. E./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736